UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,257	04/27/2007	Nobukazu Tanaka	286669US0PCT	2219

22850 7590 11/13/2009

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
MILLIGAN, ADAM C	
ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
11/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.	Applicant(s)	
	10/576,257	TANAKA ET AL.	
	Examiner	Art Unit	
	ADAM MILLIGAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 17-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1pg(4/17/2006), 2pgs(6/23/2006), 1pg(4/9/2007)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of species lactose for Group A, magnesium alumino metal silicate for Group B and (i) low-substituted hydroxypropyl cellulose and (ii) crystalline cellulose for Group C in the reply filed on 4/24/2009 is acknowledged.

Claims 14 and 15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Here, the claim recites the melting point of mannitol is depressed, but it is unclear how the mannitol per se can have a depressed melting point. Instead, the depression of the melting point appears to be directed to the mannitol-complex, not the mannitol itself, given a melting point is a set physical property of a compound given a specific melting environment. For purposes of examination, it will be presumed the depression is with regards to the complex.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless-
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-7, 10 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoshino (JP 2002/560764 – See IDS dated 4/9/2007).

Hoshino teaches a granule containing 300 mg acetaminophen, 350 mg erthritol, 200 parts mannitol, 10 mg aspartame, 50 parts hydroxypropyl cellulose and 50 parts calcium silicate (abstract).

The limitations recited by claims 4-7 are reasonably expected to be inherent properties of the prior art composition, given the composition of the prior art reads on the instant claims and the term “complex particle” is interpreted broadly to include the condition where the components are mixed together. With regard to the depressed melting point of mannitol, it is presumed the combination will have a different melting point than the mannitol alone.

With regards average pore diameter limitation of claim 10, the prior art contains aluminum silicate, which Applicants admit has an average pore diameter of 100 nm or less (see instant specification at ¶24).

Claims 16 and 17 recite product by process limitations. If the product in the product-by-process claim is the same as a product of the prior art, the claim is

unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (MPEP 2113). Here, the resulting product is expected to be the same as the prior art despite the method of production. The instant claims are simply directed to mixing via spray-drying dispersion, which results in a granule, such as disclosed in the prior art.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Claims 1-12, 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koike (WO 02/30400 - See IDS dated 4/17/2006 – References contained herein are to english equivalent document U.S. 2004/0033258).

Koike teaches a quick disintegration tablet composition comprising 40.8% Grandule D and 57.42% Granule E (Example 6, ¶¶ 262-265). Granule D comprises 60g manidipine hydrochloride (*i.e.* active), 180.6g lactose, and 51g low substituted hydroxypropyl cellulose (*id.*) Granule E comprises 266.5g of D-mannitol, and 18g of

crystalline cellulose(*id.*). Koike teaches that an alternative active agent is the antacid magnesium aluminometasilicate (¶175). The crystal cellulose may be in the form of microcrystalline cellulose.

Koike does not teach a specifically disclosed embodiment containing all of magnesium aluminometasilicate, mannitol, lactose, low substituted hydroxypropyl cellulose and crystalline cellulose.

It would have been obvious to one of ordinary skill in the art to substitute an active agent, such magnesium aluminometasilicate, from the list of actives provided by the specification into a specific embodiment disclosed where the list is provided to guide the skilled artisan in such picking and choosing. The result of such a substitution would yield a composition having about 80.4% saccharides, 11% disintegrant and 8.6% inorganic excipient. Of the saccharides, about 68% is mannitol and about 32% is lactose. Where the purpose of the tablet is to provide quick disintegration, it would have been obvious to optimize the relative amounts of the various components to reduce the disintegration time of the tablet.

The limitations recited by claims 4-7 are reasonably expected to be inherent properties of the prior art composition, given the composition of the prior art reads on the instant claims and the term “complex particle” is interpreted broadly to include the condition where the components are mixed together. With regard to the depressed melting point of mannitol, it is presumed the combination will have a different melting point than the mannitol alone.

With regards average pore diameter limitation of claim 10, the prior art contains aluminum silicate, which Applicants admit has an average pore diameter of 100 nm or less (see instant specification at ¶24).

Claims 16 and 17 recite product by process limitations. If the product in the product-by-process claim is the same as a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (MPEP 2113). Here, the resulting product is expected to be the same as the prior art despite the method of production. The instant claims are simply directed to mixing via spray-drying dispersion, which results in a granule, such as disclosed in the prior art.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koike (WO 02/30400 - See IDS dated 4/17/2006 – References contained herein are to english equivalent document U.S. 2004/0033258) in view of Ishikawa (Preparation of Rapidly Disintegrating Tablet Using New Types of Microcrystalline Cellulose (PH-M Series) and Low Substituted-Hydroxypropylcellulose or Spherical Sugar Granules by Direct Compression Method, Chem. Pharm. Bull., Vol.49, No.2, pp.134-139, 2001).

Koike is discussed above but does not teach the use of a disintegrating agent with an average particle diameter of 20μm or less.

Ishikawa teaches that the preparation of rapidly disintegrating tablets using microcrystalline cellulose having a mean particle size of 7μm (p. 134, right col.). Disintegration time was significantly shorter when small particle sizes were used (p.135,

right col., 2nd ¶). Tablets prepared using a particle size of 7μm sufficient crushing tolerance and were very rapidly disintegrated in the mouth (p.136, 1st ¶).

It would have been obvious to one of ordinary skill in the art, when making the quick release tablet of the primary reference to use known microcrystalline cellulose components, such as disclosed in the secondary reference. Additionally, the secondary reference provides additional motivation to use microcrystalline cellulose with an average diameter of 7μm due to the shortened disintegration time while still retaining sufficient crushing strength.

Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 and 16-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-28, and 30-32 of copending Application No. 10/945,049. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application is directed to tablets with the same components as instantly claimed, just in different order. Thus, it would be obvious to pick and choose from the claimed components of the copending claims to result in the instantly claimed tablet, given the components of the copending application are claimed to be useful as rapidly disintegrating tablets when combined. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ADAM MILLIGAN whose telephone number is (571)270-7674. The examiner can normally be reached on M-F 9:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612

/ADAM MILLIGAN/
Examiner, Art Unit 1612